

K090188

JUL 13 2009

510 (k) Summary

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1. Submitter Information

Company name	TaiDoc Technology Corporation
Contact person	Erica Li
Address	6F, No. 127, Wugong 2 nd Rd, Wugu Township, Taipei County, 248, Taiwan
Phone	(886-2) 6625-8188
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2. Name of Device

Trade Names	U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System
Common Names/Descriptions	Blood Glucose Meter Blood Glucose Test Strips
Classification Names	Class II devices (21 CFR Section 862.1345, Glucose Test System)

3. Predicate Device

Trade/Proprietary Name:	Clever Chek TD-4227 Blood Glucose Monitoring System
Common/Usual Name:	Blood Glucose Meter Blood Glucose Test Strips
Manufacturer	TaiDoc Technology Corporation
510 (k) Number	K072784

4. Device Description

U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System consists of a meter and test strips. The system utilizes an electrochemical method-based meter and dry reagent biosensor (test strips) for blood glucose testing. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measurement of glucose in fresh whole blood and control solutions.

5. Intended Use

U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System is indicated for the quantitative measurement of glucose in fresh capillary whole blood taken from the finger and the alternative sites for self testing by persons with diabetes in the home or by healthcare professionals in healthcare facilities. Testing is done outside the body (in vitro diagnostic use).

The alternative site testing (the palm, the forearm, the upper arm, the calf and the thigh) in this system can be used only during steady-state blood glucose conditions.

This system contains speaker function which provides step by step instructions.

6. Comparison to Predicate Device

U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System has equivalent technological characteristics as the Clever Chek TD-4227 blood glucose monitoring system (K072784). U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System also has the same intended use as the Clever Chek TD-4227 blood glucose monitoring system

7. Performance Studies

Since the change between the predicate and proposed devices is only in the brand name, the performance data of U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System can be reference to k072784.

8. Conclusion

U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System demonstrates satisfactory performance and is suitable for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Taidoc Technology Corporation
c/o Ms. Erica Li
Management Representative
6F, No. 127, Wugong 2nd Road
Wugu Township, Taipei County,
China (Taiwan) 241

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUL 13 2009

Re: k090188
Trade Name: U-Right TD-4227 No Coding Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: NBW, CGA
Dated: May 21, 2009
Received: May 26, 2009

Dear Ms. Li:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

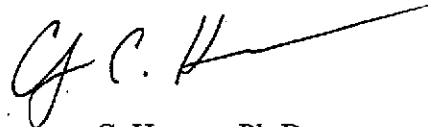
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "C.C. Harper", with a long horizontal flourish extending to the right.

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K090188

Device Name: U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System

Indications for Use:

The U-RIGHT TD-4227 No Coding Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and the following alternative sites: the palm, the forearm, the upper-arm, the calf and the thigh. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The alternative site testing in this system can be used only during steady-state blood glucose conditions.

This system contains a speaking functionality which provides step by step instructions to aid visually impaired persons.

Prescription Use X AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol Benson
Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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